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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,644	11/01/2001	Jean-Louis Bessereau	1321.2.28.1	7271

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TRASK BRITT  
P.O. BOX 2550  
SALT LAKE CITY, UT 84110

EXAMINER

SHUKLA, RAM R

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/980,644

Applicant(s)

BESSEREAU ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20,35,36 and 57-126 is/are pending in the application.
- 4a) Of the above claim(s) 57-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,35 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/17/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1632

### DETAILED ACTION

1. Applicant's response and amendment filed 9/10/04 has been received and entered.
2. The amendment and response filed 5/21/04 were held non-responsive and therefore not entered.
3. Claims 1-19, 21-34 and 37-56 have been cancelled.
4. New claims 57-126 have been added.
5. Claims 20, 35, 36, and 57-126 are pending.

6. Newly submitted claims 57-126 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly presented claims are drawn to a method wherein the transgene construct comprising an artificial intron whereas the originally claimed elected invention was drawn to a method wherein the construct comprised a 3' untranslated region of a gene. These two invention therefore are drawn to patentably distinct inventions that would require separate and non-coextensive search in the patent and non-patent literature.

Applicants' arguments that the newly presented claims relate to a single general invention concept are not persuasive because the requirement for unity of invention is not a general inventive concept, rather it is the presence of same specific technical feature, which in the instant case is lacking. Therefore, applicants' arguments are not persuasive and the lack of unity requirement and that the newly presented claims are drawn to different invention than originally elected are maintained.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 57-126 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7. Claims 20 and 35-36 drawn to a method of transposon-mediated mutagenesis in a *C. elegans* genome by introducing a transgene comprising a transposase operably linked to a promoter and a 3' untranslated region of a *C. elegans* gene are under consideration.

8. Applicants' amendment of the specification regarding the cross reference of related applications has been entered.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 20 and 35-36 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record set forth in the previous office action of 2/25/04. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Response to Arguments***

Applicant's arguments filed 9/10/04 have been fully considered but they are not persuasive. Applicants arguments that since the basic functional characteristics of a 3' UTR are known, description of three species are sufficient description are not persuasive because applicants did not provide any factual evidence to support the statement that basic functional characteristics of a 3'UTR are known. Further, applicants argument that Gallegos et al teaches a fourth 3' UTR does not address the description requirement because claims encompass any gene that is expressed in C.elegans germ line and applicants did not provide any evidence that these four are representative of the entire genus of genes expressed in C.elegans germ line.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1632

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 20 and 35-36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Plasterk et al (US 6,051,430, 4-18-00) in view of Vos et al (Genes and Development 10:755-761, 1996), Van Leunen et al<sup>1</sup> (Cell 79:293-301, 1994), Van Leunen et al<sup>2</sup> (The EMBO Journal 12:2513-2520, 1993), Hackett et al (US 6,489,458 B2, 12-3-2002, filing date 3-11-1998) and Gallegos et al (The EMBO Journal 17:6337-6347, 1998) for reasons of record set forth in the previous office action of 2/25/04.

### ***Response to Arguments***

Applicant's arguments filed 9/10/04 have been fully considered but they are not persuasive. Applicants' arguments that Pasternak et al does not disclose Tc1 in *C. elegans* is not persuasive because the transposon and transposase was isolated from *C. elegans* and was expressed in somatic cells of *C. elegans*. Primary purpose of Pasternak being gene therapy is irrelevant because the art of Pasternak has to be considered as a whole which teaches the Tc1 and its activity in *C. elegans*. Furthermore, it is noted that the rejection is not a 102, not a 103. Applicants' arguments that the cited arts do not teach artificial intron are irrelevant since the claimed invention does not recite any such limitation. Regarding applicants arguments that Gallegos does not teach germ line expression and rather teaches away from germ line expression, applicants are directed to different to different parts of the art, such as page 6343, last paragraph in the right hand column, which teaches expression in all the cells including germ cells. Further, applicants are directed to the materials and methods section on page 6345 which teaches method of producing transgenic animals, which clearly indicates germ line expression of the transgene. It is reiterated that in contrast to applicants' arguments cited arts teach the respective elements of the claimed invention as discussed in the previous office action and as discussed in the previous office action, at the time of the invention, it would have been obvious to an artisan of skill to modify the vector of Plasterk et al or Vos et al or Van Luenen et al<sup>2 or 1</sup> by adding the 3' untranslated region of *fem-3* and using different inducible transcriptional control system such as tet-based system with a reasonable expectation of success. An artisan would have been motivated to modify the vector because this would have allowed to integrate the vector in the germ line and being heat shock responsive it would provide double control.

Applicants' arguments regarding long-felt need for a mutational system for *C.elegans* are not persuasive because it does not make the claimed invention non-obvious.

13. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

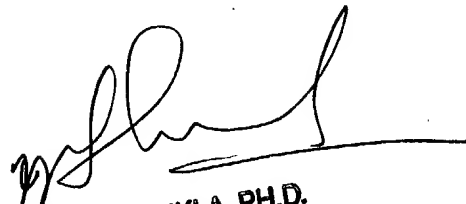
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

Art Unit: 1632

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Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632



RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER